b. selecting a second amphiphilic lipid component and selecting at least one active ingredient; or

c. selecting an amphiphilic active ingredient to form a second amphiphilic lipid component, and optionally selecting one or more further active ingredients;

d. said first and second amphiphilic lipid components being selected so that the solubility of the second amphiphilic lipid component in a pharmaceutically acceptable suspending medium is at least ten times greater than the solubility of the first amphiphilic lipid component in said medium;

e. adapting the composition or concentration of the preparation for transport through skin or mucous membrane, by adjusting the content of the more soluble component to less than 0.1 mole percent of the content of the first and second amphiphilic lipid components at which the enveloped droplets stabilize, if there is a solubilizing point; and

f. adjusting the content of amphiphilic lipid components, such that the ratio of the permeation capability relative to reference particles which are much smaller than the constrictions of the barrier, wherein the reference particles are water, is between 10^{-5} and 1;

g. producing a transfersome suspension by means of applying energy to the mixture of said amphiphilic lipid components including at least one active ingredient, said transfersomes comprising liquid droplets encompassed within a sheath comprising said amphiphilic lipid components, said amphiphilic lipid components being selected such that said transfersomes are capable of undergoing sufficient deformation to pass through said skin or mucous membrane without being solubilized, said active ingredient being contained in said liquid droplets, or in said sheath, or in both said liquid droplets and said sheath.

24. The method of claim 22 wherein stability and permeation capability are determined by filtration under pressure through a filter having pore size ranging from about 30 to about 100 nm or by controlled mechanical whirling up, shearing or comminuting.

73 33. The method of claim 22, wherein shortly before use, the enveloped droplets are prepared from a concentrate or lyophilisate.

Please add the following new claims:

91. The method of claim 90, wherein the ratio of the permeation capability relative to reference particles which are much smaller than the constrictions of the test barrier is between 10^{-2} and 1.

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92. The method of claim 22, wherein the transfersomes are produced by a method selected from the group consisting of filtration, treatment with ultrasound, stirring and shaking

REMARKS

Claims 22-33 and 49-90 are pending in the subject application. Claims 22, 24, 33 have been amended for clarification purposes and for purposes of correcting typographical errors. Claims 91-92 have been added. Support for the amendment to claims 22, 24 and 33 and added claim 91-92 is found throughout the Specification, as filed, and no new matter is presented by the amendment.

Enclosed herewith for the Office's consideration is an English translation of the EP 0 475 160 reference.

Favorable reconsideration in light of the amendments and remarks which follow is respectfully requested.

1. 35 U.S.C. §112 Rejections

Claims 22-33 and 49-52 have been rejected under 35 U.S.C. §112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.